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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/910,485 | 07/20/2001 | Mark B. Lyles | 068986.0102 | 1620 |

7590 07/25/2003

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| EXAMINER |
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SULLIVAN, DANIEL M

| ART UNIT | PAPER NUMBER |
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1636

17

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/910,485 | LYLES, MARK B. |
| | Examiner Daniel M Sullivan | Art Unit 1636 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 5-17,35-40,42,47 and 53-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 5-17,36-40 and 42 is/are allowed.
- 6) Claim(s) 35,47,53,55-63,66 and 69 is/are rejected.
- 7) Claim(s) 54,64,65,67 and 68 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Non-Final Office Action is a response to the “Response to Office Action...” filed 13 May 2003 (Paper No. 16) in reply to the Non-Final Office Action mailed 13 January 2003 (Paper No. 13). Claims 5-17, 35-40, 42, 47 and 53-64 were considered in Paper No. 13. Claims 5, 7, 40, 42, 47 and 54 were amended and claims 65-69 were added in Paper No. 16. Claims 5-17, 35-40, 42, 47 and 53-69 are pending and under consideration.

Response to Amendment

Objection to claims 5 and 40 as containing informalities is withdrawn.

Rejection of claim 54 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn.

Rejection of claim 54 under 35 U.S.C. 102(b) as anticipated by Li *et al.* (1996) WO 96/01617 is withdrawn in view of the amendment to the claim.

Claims 47, 53, and 55-63 stand rejected under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (1996) WO 96/01617 for reasons set forth in Paper no. 13 and herein below in the “Response to Arguments”.

New grounds for rejection are set forth herein below.

Response to Arguments

In response to the rejection of claims 47, 53, and 55-63 under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (1996) WO 96/01617, Applicant has amended claim 47 to be limited to providing a formulation “consisting essentially of nucleic acids having greater than 5000 bases”. Applicant argues that the claim now reads on a formulation consisting essentially of “nucleic acids having an average of greater than 5000 base pairs” (page 7, emphasis added). This argument has been fully considered but is not found persuasive. First, the formulation is not limited to consisting essentially of nucleic acids having an average of greater than 5000 base pairs, but to consisting essentially of nucleic acids having greater than 5000 base pairs. Next, the MPEP states, “[f]or the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, ‘consisting essentially of’ will be construed as equivalent to ‘comprising’” (§ 2111.03). As the basic and novel characteristics of nucleic acids having greater than 5000 base pairs is not clear from the disclosure, the transitional phrase “consisting essentially of” is construed as equivalent to “comprising”. Thus the formulation of the claims is understood to be limited to comprising nucleic acids having greater than 5000 bases, and the method disclosed by Li *et al.* anticipates the claims for the reasons set forth in Paper No. 13.

New Grounds

Claim Objections

Claims 5, 47, 65, 66, 67 and 69 are objected to because of the following informalities:

The word “retinoic acid is misspelled in claim 5.”

The comma following "nucleic acids" in the third line of claim 47 is grammatically incorrect.

The words "phenylalanine", "collagen" and "retinoic acid" are misspelled in claim 65.

The phrase "thymidine dimers" is misspelled in claim 66.

The word "cholesteric" is misspelled in claim 67.

The word "sulfoxide" is misspelled in claim 69.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are directed to methods comprising providing a formulation comprising nucleic acids modified by ethylation, cross linking, ultraviolet cross-linking, or the formation of thymidine dimers. There is no support for a formulation comprising nucleic acids modified by ethylation, cross linking, ultraviolet cross-linking, or the formation of thymidine dimers in the originally filed disclosure. Thus, the limitations constitute new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 66 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (1996) WO 96/01617 for reasons set forth in the rejection of the base claim 47 in Paper No. 13 and herein above.

Claim 66 is directed to the method of claim 47 wherein the nucleic acids are modified in various ways. On page 15, paragraph 2, Li *et al.* teaches that the DNA mixture can be irradiated under a UV light source, which is known in the art to induce cross-linking and the formation of thymidine dimers in DNA. Further, in Examples 3, 4 and 5, Li *et al.* teaches cross-linking of DNA to various solid supports.

Claim 69 is directed to the method of claim 47 wherein the formulation further comprises various compounds including water, alcohols, water-soluble alcohols, dimethyl sulfoxide, buffers and perfumes. Li *et al.* teaches formulations comprising each of these compounds (see especially the paragraph bridging pages 9 and 10 and formulas A, B and C on page 16).

The nucleic acids and formulations taught by Li *et al.* are the same as the nucleic acids and formulations of the instant claims; therefore, the limitations of the claims are anticipated by Li *et al.*

Allowable Subject Matter

Claims 5-17, 36-40 and 42 are allowed.

Claims 54, 64, 65, 67 and 68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

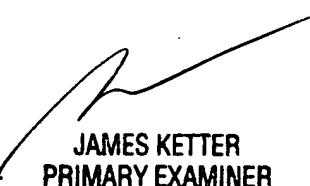
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
July 16, 2003



JAMES KETTER
PRIMARY EXAMINER